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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/489,982	
	Filing Date	January 21, 2000	
	First Named Inventor	STOLL, Thomas G	
	Art Unit	3625	
	Examiner Name	BLECK, Carolyn	
Total Number of Pages in This Submission	50	Attorney Docket Number	2139.00

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
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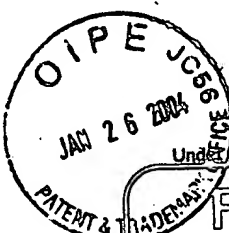
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	David E. Herron II PO Box 2778 Kansas City, KS 66110
Signature	
Date	January 24, 2004

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Signature		Date	01/24/04

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 165.00

Complete if Known

Application Number 09/489,982
Filing Date January 21, 2000
First Named Inventor STOLL, Thomas G
Examiner Name BLECK, Carolyn
Art Unit 3626
Attorney Docket No. 2139.00

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METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number
Deposit Account Name

502643

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below	Fee Paid
Independent	Multiple Dependent	-20** =	-3** =		

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	165.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 165.00

SUBMITTED BY

Name (Print/Type) David E. Herron II

Registration No. 46467
(Attorney/Agent)

Telephone 913-371-7011

Signature

David E. Herron II

Date January 25, 2004

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#33/appeal Brief
J. Ellis
2-18-04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: STOLL, Thomas G. et al Art Unit: 3626
SERIAL NO 09/489,982 Examiner: C. Bleck
FILED : January 21, 2000
TITLE: DIGITAL PRESCRIPTION CARRIER AND METHOD

Mail Stop Appeal
Assistant Commissioner for Patents
PO Box 1450
Alexandria, VA 22313

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APPEAL BRIEF

Dear Sir:

Below is an Appeal Brief in support of an appeal taken from the Final Rejection issued on August 27, 2003, denying the patentability of claims 1-21. A Notice of Appeal was deposited in United States Mail on November 27, 2003, and was received by the Commissioner on December 1, 2003.

1. **Real party in interest.** All rights in this application have been assigned to NextMed, LLC, a limited liability company existing by virtue of Missouri law.

2. **Related appeals and interferences.** There are no related appeals, and no related interferences.

3. **Status of Claims.** The application contains claims 1-21.

Claims 1-21 stand rejected as obvious under 35 U.S.C. 103(a) over the combination of Gombrich et al '372, Leigh-Spencer '802, and an article published by the Computer Science Telecommunication Board National Research Council.

Claims 1-21 stand rejected as unpatentable under 35 USC 103(a) as obvious in view of Goetz '190 in view of an article published by the Computer Science Telecommunication Board National Research Council.

Claims 1-21 stand rejected as unpatentable under 35 USC 112 as failing to distinctly claim the invention and/or fail to contain an enabling disclosure.

Additionally, Claims 1, 7, and 14 stand rejected under 35 USC 132 as being introducing amendments which are unsupported by the disclosure, as initially filed.

4. **Status of Amendments.** All amendments filed by Applicants have been entered and considered by the examiner.

On August 27, 2003, a Final Rejection of all pending claims was issued. On September 26, 2003, the Applicants filed an Amendment After Final.

On October 20, 2003, the Examiner issued an Advisory Action informing that the Amendment After Final, filed on September 26, 2003, was entered into the record, but that the Final Rejection was, in all ways, affirmed.

The Applicants filed a Notice of Appeal on November 25, 2003.

5. **Summary of the Invention.**

Referring to Figure 1, the invention is a digital prescription carrier 1 that is adapted to have prescription data uploaded thereinto from a physicians computer for transportation to a pharmacy, at which the data may be downloaded into a pharmacist's computer. There, the data is accessed, and the prescription filled.

Still referring to Figure 1, the carrier 1 includes a housing 2 having a liquid crystal display 3, and operation buttons 4. The housing 2 also includes an alert device selection switch, a sonic output device, and an infrared interface window 7,8.

Referring to Figure 2, a battery (not pictured) will be within the housing 2 (shown Fig 1) and will empower circuitry 20, which will include a low battery detector power supply 21. The circuitry 20 includes a CPU 24, which may be either a microprocessor or a microcontroller. The CPU includes, among other on-chip components, non-volatile RAM memory 26, and a real-time clock calendar 27. The CPU may also include or be interfaced with ROM and/or conventional memory or RAM.

Still referring to Figure 2, the software 30 (Fig that operates the carrier is stored in the non-volatile RAM 26 (shown in Fig 2). The operation buttons or switches 4 (from Fig 1) are interfaced to the CPU 24. Additionally, the LCD display 3 is also interfaced to the CPU. LCD Driver Circuitry 32 interfaces the display circuitry 3 to the CPU. The display may also include a backlight switch 18, a delay switch 16, a take switch 17, and an alert select switch 5. The backlight switch 18 toggles one or more light emitting diodes that illuminate the display to ease the reading of the display in darkness.

Referring to Figure 3, the software 30 executed by the CPU 24 of the carrier 1 (see fig 1) is able, with the cooperation of the real-time clock-calendar 27, to track schedules for a plurality of medicines.

As shown in Figure 3, when the IR data link 46 is activated, a communication test run is performed. If proper communication is established a security test 54 is entered, which requires the entry of a valid encryption key or password. If the encryption key is

NOT correct, the communication between the carrier 1 and the external source 44 is disabled at 66.

Still referring to Figure 3, it is important to note that, in the present invention, an encryption key is REQUIRED to perform any of the uploading or downloading steps, which entitle a prescriber or a pharmacist to enter and alter the digital data within the carrier's software 30. If the encryption code entered is valid, then either the doctor mode (68) or the pharmacy mode (69) is entered. In the pharmacy mode, the pharmacist may access all the current prescriptions, and decrement refill counts of certain prescriptions, and view patient information stored in the carrier (see Fig 1). The data link 46 gives the carrier 1 the capability of being accessed remotely (such as over the internet) for the entry or modifications of prescription data by a physician, or review of compliance data by either the physician or pharmacist.

6. Issues on appeal.

Whether Claims 1-21 are unpatentable under 35 USC 103(a) as obvious in view of Goetz '190 in view of an article published by the Computer Science Telecommunication Board National Research Council.

Whether Claims 1-21 are unpatentable under 35 USC 112 as failing to distinctly claim the invention and enable one skilled in the art to make and use the claimed invention.

Whether amendments to Claims 1, 7, and 14 introduce new matter that was not set forth in the original disclosure, as initially filed.

7 Grouping of claims.

The Applicant asserts that each claim set forth herein is separately patentable, and that none of the claims stand or fall together. Rather, each respective claim should stand or fall on its own merits because the cited prior art fails to show, teach, suggest, or disclose the combination of elements and limitations set forth in any single claim.

8. Argument

I.

**THE FINAL REJECTION ERRONEOUSLY REJECTED
CLAIMS 1-21 AS OBVIOUS OVER THE
COMBINATION OF GOETZ IN VIEW OF AN ARTICLE
PUBLISHED BY THE COMPUTER SCIENCE
TELECOMMUNICATIONS BOARD.**

A.

**BECAUSE THE APPLICANTS HAVE SUBMITTED
RESPECTIVE AFFIDAVITS SWEARING THAT
THE SUBJECT MATTER WAS REDUCED TO
PRACTICE PRIOR TO JANUARY OF 1997,
GOETZ IS NOT PRIOR ART**

On June 10, 2003, the Applicants submitted revised affidavits along with an Amendment. The Board will note that Applicant Tom Stoll had submitted an affidavit on a prior occasion, but because the claims had been amended with the paper simultaneously filed on June 10, 2003, the Affidavit was likewise revised to establish that the Applicants reduced the invention – as set forth by the newly-amended claims – prior to December of 1997.

The Supervisory Examiner inexplicably asserts that Karl P Schmidt is not an inventor. Despite diligent research, the undersigned cannot find a single paper that supports the Supervisory Examiner's contention. First, the Affidavit of Karl P. Schmidt itself indeed states that he is an inventor. Second, Applicant Karl P. Schmidt submitted a Declaration swearing that he is a joint inventor. Without reason, the Supervisory Examiner elected to disbelieve Mr. Schmidt's duly executed Declaration which asserts

that he is a joint inventor. Additionally, the Supervisory Examiner enumerated no papers establishing Mr. Schmidt's deletion as an inventor.

It is respectfully requested, in response to this Appeal Brief, that the Supervisory Examiner submit an Examiner's Answer that explains -- to the Applicant and to this panel -- the reasons for disbelieving the Declaration submitted by Applicant Schmidt. Alternatively, the Applicant respects that the Supervisory Examiner provide the authority entitling a member of the examining corps to unilaterally, whimsically, arbitrarily, and capriciously strike an inventor from an application.

B.

**THE FINAL REJECTION ERRONEOUSLY
REQUIRED CORROBORATING EVIDENCE TO
ACCOMPANY THE AFFIDAVIT SUBMITTED
UNDER 37 CFR 1.131**

In *ex parte* prosecution of an application, corroborating evidence in the form of documents is not required. *See, e.g.,* MPEP 715.07; *see also, Ex parte Hook and Crook*, 102 USPQ 130 (Bd. Pat. App. 1953). In accord with this authority that was discussed at the interview, the affidavits will be given full credence, and the applicants will be allowed to stand on the averments set forth therein standing alone.

The Applicants' sworn testimony confirms that *each and every claimed element* was in possession of the applicants, and in fact reduced to practice prior to the effective filing date of Goetz. Consequently, the affidavit is not only sufficient in form, but also substantively eliminates Goetz as prior art. Additionally, the affidavit of Mr. Stoll further establishes that, in the event there are differences between the subject matter set forth in

the claims and the subject matter set forth in the affidavit, then these differences – if any are found – are merely obvious variations of the claimed invention, and would have been obvious to one having ordinary skill in the applicable art. As such, Goetz is not prior art.

Instead of applying well-settled law, as set forth in the MPEP and in *Hook & Crook (supra)*, the Final Rejection whimsically and curiously elects to make new law by manufacturing a new requirement for corroboration. Alternatively, the Supervisory Examiner opted to disbelieve the sworn, uncontroverted, and unopposed testimony of the Applicants. In *ex parte* prosecution, such a stance is improper. The finding of insufficiency must be reversed.

The Final Rejection based its erroneous finding of insufficiency upon an incorrect premise: that Mr. Stoll failed to enumerate facts in his Affidavit. Indeed, *paragraph 2* of Mr. Stoll's Affidavit alone recites twenty-one individually-enumerated facts. Further, *paragraph 5* of Mr. Stoll's Affidavit itself recites eighteen (18) individually-enumerated facts. These facts, taken as true, show that the invention was completed and reduced to practice no later than December of 1997.

C.

ASSUMING, ARGUENDO, THAT AFFIDAVITS SUBMITTED UNDER 37 CFR 1.131 REQUIRE CORROBORATION, A REQUIREMENT FOR CORROBORATION HAS CLEARLY BEEN MET BY THE DOCUMENTS SUBMITTED WITH THE AFFIDAVITS FILED IN THIS CASE.

Even if this Board should determine that the statements of the Applicants, standing alone, fail to disqualify Goetz as prior art, the corroboration submitted with the Affidavits clearly establishes invention of the claimed subject matter before Goetz' filing date..

Referring specifically to the Affidavits and the exhibits thereto, attention is invited to the letter from Kemnitzer Design, Inc., dated December 1997. This paper clearly establishes that the Applicant had *at least eleven of the claimed limitations* in his possession at least as early as December 17, 1997. Even though Applicant had already reduced to practice his entire invention, and therefore ALL of the claimed limitations were in his possession prior to December 1997, this Kemnitzer letter establishes *eleven distinct limitations* of applicant's claimed invention *in a writing that predates Goetz*. The remaining elements that were not mentioned by the drafter of the Kemnitzer letter were evidently overlooked by the drafter of the Kemnitzer letter, even though these already-existing elements form important parts of the inventive combination.

The affidavit also incorporates a Medx System Flow Chart that was created prior to December of 1997. Even though the Applicant had already reduced to practice his entire invention, and therefore all of the claimed limitations were in his possession before

December of 1997, the flowchart clearly establishes that *at least ten of the claimed limitations* were in Applicant's possession prior to December of 1997.

Accompanying documents and exhibits, if submitted by an Applicant, need not support all of the claimed limitations. See, e.g., MPEP 715.07 at p. 700-210, Col 1, citing *Ex Parte Ovshinsky* 10 USPQ2d 1075 (Bd. Pat. App. 1989). Instead, any limitations missing from the document should be supported by the declaration itself. *Id.* In the instant case, **EACH AND EVERY CLAIMED LIMITATION** is set forth within the Affidavit itself, and each and every claimed limitation is shown to be part of the combination of elements that was assembled together and reduced to practice before December of 1997.

In several paragraphs on pages 40 and 41, the Final Rejection erroneously misplaces the burden of proof with regard to a potential public disclosure of the invention. Indeed, the Supervisory Examiner demanded that the Applicants establish that there was NO PUBLIC DISCLOSURE that would act as a bar to patentability. However, the Office bears the burden to come forward with evidence that negates patentability. The Applicant and counsel concede the continuing duty of candor to the Office by disclosing information that pertains to patentability. True, there has in fact been no public disclosure of the claimed invention that bars patentability; however, the requirement to provide documentation of the absence of public disclosure is wholly absent from patent practice.

In paragraph (g) on page 42, the Final Rejection admits that the Affidavit and Exhibits to establish a conception that predates Goetz, but that the Affidavit fails to establish a reduction to practice. However, attention is invited to the pre-amble to

paragraphs 2 and 5, which state “ *[n]o later than December, 1997, I reduced to practice the following elements of a digital prescription carrier apparatus...* ” The assertion that there is no evidence of reduction to practice is clearly misplaced – in fact, reduction to practice is unambiguously set forth in no uncertain terms. In order to find that there is NO evidence of reduction to practice, the Supervisory Examiner would have to elect to disbelieve the sworn, unopposed, and uncontradicted testimony of the Affiant.

Noting that the Supervisory Examiner also elected to disbelieve Mr. Schmidt’s Declaration without reason or justification, it must be asserted that the Supervisory Examiner has a clear bent to disbelieve the sworn testimony of the Applicants hereto. During *ex parte* prosecution of an application, the Supervisory Examiner has neither the discretion nor the option of disbelieving the Applicants’ sworn and unopposed statements. *Ex parte Hook and Crook*, 102 USPQ 130 (Bd. Pat. App. 1953).

Because the Supervisory Examiner acted outside of the requirements to adhere to well-settled law, and instead elected to use the pending application to suit his own personal ideals, the finding of insufficiency should be reversed, and the matter remanded to the Examiner, along with instructions to refrain from departing from well-settled law at the expense of customers of the United States Patent & Trademark Office.

D.

EVEN IF GOETZ QUALIFIES AS PRIOR ART, THE REJECTION OF CLAIMS 1-21 AS OBVIOUS OVER GOETZ AND THE ARTICLE OF THE COMPUTER SCIENCE TECHNOLOGY BOARD IS IMPROPER BECAUSE GOETZ AND THE ARTICLE FAIL TO ESTABLISH PRIMA FACIE OBVIOUSNESS OF THE CLAIMED COMBINATION.

Claim 1 is drawn to a method including the steps of providing a digital prescription carrier including a read/write memory and an infrared communication interface, and uploading prescription data defining a prescription into the carrier through the interface., such that the prescription called for the use of a selected medication of a selected dosage on a selected schedule. In contrast, Goetz shows that data is contained within a card that can be inserted into *any one of the handler's carrier 12, the veterinarian's carrier 16, or the veterinarian's computer 18*. Because Goetz discloses an invention having several distinct carriers, it teaches away and cannot suggest the claimed combination set forth in Claim 1.

The Article cited deals exclusively with encryption and decryption technologies. Indeed, the Final Rejection proffers this reference for that purpose. As such, this Article neither discloses, teaches, nor suggests the items absent from Goetz. Consequently, the article of the Computer Science Telecommunications Board and Goetz fail to combine to establish prima facie obviousness of Claim 1. See, e.g., M.P.E.P 2142; see also, *In re Vaeck*, 947 F.2d 488 (Fed Cir. 1991).

Consequently, claim 1 is allowable over Goetz and the Article. Claims 2-6, 20, and 21 which further limit Claim 1, should also be allowed for their separate, patentable limitations.

Claim 7 is drawn to a method including, *inter alia*, the steps of providing a digital prescription carrier including a read/write memory and a communication interface, and entering a first access code into the carrier to enable software access thereto, and uploading prescription data into the carrier through the interface and downloading the prescription data from the carrier through the interface at the pharmacy.

In contrast, Goetz teaches a system having at least two distinct carriers 12, 16. Because Goetz teaches distinct carriers, it cannot teach, suggest or disclose a method including the step of uploading prescription data defining a prescription into a carrier through an interface, and further including the step of downloading the prescription data from the carrier through the interface. Instead, Goetz teaches the uploading of data while using a first carrier, and the downloading of data using a second carrier. Consequently, Goetz does not teach, suggest or disclose each and every limitation set forth in the claims.

The Final Rejection does not apply the cited Article to teach, suggest, or disclose these aforementioned claimed limitations that were absent from Goetz. Indeed, the Final Rejection applied the Cited Article to teach encryption and decryption technologies. As such, the Article and Goetz cannot combine to establish the prima facie obviousness of Claim 7. Consequently, Claim 7 is allowable over this combination. Claims 8-13, which further limit Claim 7, are likewise allowable for their respective separate, patentable limitations.

Claim 14 is drawn to digital prescription carrier apparatus having, inter alia, a carrier housing, and a central processing unit (CPU) positioned within the housing, and an input/output (I/O) interface circuitry positioned in the housing and interfaced to the CPU. The claim also includes data memory circuitry positioned within the housing. The claim requires the CPU and the I/O circuitry cooperate to enable uploading, by a prescriber, of the prescription data into the memory circuitry, and downloading of the prescription data at a pharmacy.

In contrast, Goetz teaches a system having at least two distinct carriers 12, 16. Because Goetz teaches distinct carriers, it cannot teach, suggest or disclose a method including the step of uploading prescription data defining a prescription into a carrier through an interface, and further including the step of downloading the prescription data from the carrier through the interface. Instead, Goetz teaches the uploading of data while using a first carrier, and the downloading of data using a second carrier. Consequently, Goetz does not teach, suggest or disclose each and every limitation set forth in claim 14.

The Final Rejection does not apply the cited Article to teach, suggest, or disclose these aforementioned claimed limitations that were absent from Goetz. Indeed, the Final Rejection applied the Cited Article to teach encryption and decryption technologies. As such, the Article and Goetz cannot combine to establish the prima facie obviousness of Claim 14. Consequently, Claim 14 is allowable over this combination. Further, Claims 15-19 which further limit Claim 14, are likewise allowable for their respective separate, patentable limitations.

II.

THE FINAL REJECTION ERRONEOUSLY REJECTED CLAIMS 1-21 UNDER 35 USC §103(a) AS UNPATENTABLE OVER THE COMBINED TEACHINGS OF GOMBRICH '372, LEIGH-SPENCER '802, AND A PUBLICATION OF THE COMPUTER SCIENCE TELECOMMUNICATIONS BOARD, BECAUSE THESE REFERENCES FAIL TO ESTABLISH PRIMA FACIE OBVIOUSNESS.

In order to establish prima facie obviousness, the examiner must establish the following three elements:

1. The prior art references must combine to teach or suggest all the claimed limitations; and,
2. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and,
3. There must be a reasonable expectation of success in achieving the claimed combination.

See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed Cir 1991); see also, M.P.E.P.

2142.

If any one of the above listed elements cannot be met by the prior art, the references therefore fail to establish the prima facie obviousness of the claimed invention. In the instant case, the applied references fail to establish prima facie obvious, primarily because the combination of references fails to teach or suggest each and every claimed limitation.

A.

THE FINAL REJECTION ERRONEOUSLY REJECTED CLAIMS 1-6, 20 AND 21 AS OBVIOUS OVER THE COMBINED TEACHINGS OF GOMBRICH, LEIGH-SPENCER, AND AN ARTICLE PUBLISHED BY THE COMPUTER SCIENCE TELECOMMUNICATIONS BOARD BECAUSE THESE REFERENCES FAIL TO ESTABLISH PRIMA FACIE OBVIOUSNESS OF THE CLAIMED ELEMENTS

1.

GOMBRICH, LEIGH-SPENCER, AND THE ARTICLE PUBLISHED BY THE COMPUTER SCIENCE TELECOMMUNICATIONS BOARD FAIL TO SHOW, TEACH, OR SUGGEST EACH AND EVERY CLAIMED LIMITATION

Claim 1 is drawn to a method including, inter alia, the steps of

- (i) uploading prescription data defining a prescription into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule, and
- (ii) downloading said prescription data from said carrier through said interface at said pharmacy.

Gombrich '372 does not show, suggest, or disclose a method including the step of uploading prescription data defining a prescription into the carrier through the interface. Instead, Gombrich shows a Portable Handheld Patient Terminal having the ability to read bar-coded information that may be stored in a central computer. In fact, Gombrich has no suggestion that this bar-coded information may include uploaded data in the form of a prescription calling for the use of a selected medication of a selected dosage on a selected schedule.

Instead, Gombrich suggests that prescriptions should be written by prescribers, but that hospital staff should use the PHPT to print a bar code that may be affixed to the doctor's written prescription so that patient information may be paired with the information within the hospital's central computer, and this central computer info will be available to the pharmacist. See, Gombrich, Col 14, lines 40 - Col 15, line 10.

Additionally, Gombrich does not teach, suggest, or disclose a method including the step of downloading the prescription data from the carrier. Rather, as set forth in the above discourse, Gombrich teaches affixing a bar-code label to each prescription, thus enabling the pharmacist to access data within the central computer from a terminal located at the pharmacy. See, Gombrich, Col. 14, lines 60 - Col 15, line 10.

Further, Gombrich does not teach suggest or disclose a method including the step of downloading prescription data through an interface at a pharmacy. Instead, Gombrich shows a separate communications port 368 -- separate from the bar code reader -- having a multipin connector. See, Gombrich, Col 24, lines 19-28.

The Final Rejection proffered Leigh-Spencer to teach the modification of Gombrich to include transferring the carrier by a patient to a pharmacy. In contrast, the

Final Rejection did not proffer Leigh-Spencer to establish either of the above-referenced limitations that are missing from Gombrich. To wit, Leigh-Spencer neither shows nor teaches the step of uploading prescription data defining a prescription into the carrier through the interface. Rather, Leigh-Spencer discloses an invention that may be programmed to provide specific times to remind a patient to take medicine. See, e.g., Leigh-Spencer, Col 1, lines 10-12.

The Computer Science Telecommunications Board publication neither shows nor teaches the step of uploading prescription data defining a prescription into the carrier through the interface; this step, as alluded to above, was missing from Gombrich and Leigh-Spencer. Further, this Article fails to teach or suggest the step of downloading prescription data from a carrier through an interface at a pharmacy. Instead, the Article contains a detailed discussion of encryption technologies, but does not cure the deficiencies in Gombrich or Leigh-Spencer. As such, Claim 1 is allowable over the combination of Gombrich, Leigh-Spencer, and the article published by the Computer Science Telecommunications Board.

2.

**THERE IS NO SUGGESTION OR MOTIVATION
TO COMBINE THE TEACHINGS OF THE
COMPUTER SCIENCE TECHNOLOGY BOARD
ARTICLE WITH THE DISCLOSURE OF
GOMBRICH OR LEIGH-SPENCER.**

The Computer Science Telecommunications Board makes reference to the state of encryption technologies, but there is no teaching or suggestion whatsoever of using this encryption technology in combination with any of the elements set forth as claimed elements of the applicants invention. Indeed, this article contains no suggestion that this encryption technology could be used in combination with a carrier that can receive uploaded prescription data through an interface, then be transferred by a patient to a pharmacist. Without the suggestion, the cited art fails to establish prima facie obviousness with respect to claim 7. As such, claim 7 is allowable over the cited art.

Claims 2-6, 20 and 21 which further limit Claim 1, are likewise allowable for their separate, patentable limitations.

With specific reference to Claim 21, which depends from Claim 1, neither the Gombrich patent, nor the Leigh-Spencer patent, nor the Computer Science Telecommunications Board Article disclose, teach or suggest the following step:

updating, by a prescriber, of prescription information including at least one of

- deleting a piece of stored prescription data;
- adding a new piece of stored prescription data;
- changing a piece of stored prescription data.

With further regard to Claim 21, which depends from Claim 1, neither the Gombrich patent, nor the Leigh-Spencer patent, nor the Computer Science Telecommunications Board Article disclose, teach or suggest the following step:

updating, by the pharmacist, of prescription information including at least one of

- (i) noting the filling of a prescription;
- (ii) reducing the number of refills remaining for a piece of stored prescription data; or,
- (iii) updating patient information.

Because the Final Rejection fails to establish that these elements are present in any of Gombrich, Leigh-Spencer, or the Computer Science Technology Board article, the Final Rejection of Claim 21 should be reversed.

B.

THE FINAL REJECTION ERRONEOUSLY REJECTED CLAIMS 7-13 AS OBVIOUS OVER THE COMBINED TEACHINGS OF GOMBRICH, LEIGH-SPENCER, AND AN ARTICLE PUBLISHED BY THE COMPUTER SCIENCE TELECOMMUNICATIONS BOARD BECAUSE THESE REFERENCES FAIL TO COMBINE TO ESTABLISH PRIMA FACIE OBVIOUSNESS OF THE CLAIMED COMBINATION

Claim 7 was rejected as obvious over the combination of Gombrich, Leigh-Spencer, and the article published by the Computer Science Telecommunications Board. This rejection is misplaced and should be reversed.

Claim 7 is drawn to an inventive method including, inter alia, the following method steps:

- (i) uploading prescription data defining a prescription, said data being in a wholly intangible digital form, into said carrier through said interface; and,
- (ii) downloading said prescription data, said data being in a wholly intangible digital form, from said carrier through said interface at said pharmacy.

Gombrich does not teach or disclose the step of uploading wholly intangible, digital-form data into a carrier through an interface. Instead of uploading data that is in a wholly intangible digital form, Gombrich shows that data must be read by a bar code that is printed on a label or a paper. See, Col. 14, lines 60 - Col 15, line 10. Further,

Gombrich shows a Portable Handheld Patient Terminal having the ability to read bar-coded information to be stored *in a central computer*. See, e.g., Gombrich, Col 19, lines 3-10; see also, Col 23, lines 51-64.

Further, Gombrich shows that the data may be put into bar-code form and printed onto labels. Clearly, this aspect of Gombrich teaches away from the claimed limitation of uploading data in a wholly intangible form into the carrier. In addition, Gombrich has no suggestion that this bar-coded information may include uploaded data in the form of a prescription calling for the use of a selected medication of a selected dosage on a selected schedule.

The Final Rejection applied Leigh-Spencer to the rejection of claim 7 to teach a module that can be carried by a patient to a pharmacy; the Final Rejection similarly applied Leigh -Spencer to claim 1. Thus, the Final Rejection did not proffer Leigh-Spencer to teach the step of uploading wholly intangible digital prescription data into a carrier through an interface. Conversely, the Final Rejection did not proffer Leigh-Spencer to teach the step of downloading wholly intangible digital prescription data into a carrier through an interface. Indeed, Leigh-Spencer does not teach or disclose these elements that are missing from Gombrich.

The Final Rejection further applied the article from The Computer Science Telecommunications Board to teach encryption and decryption technology. However, this article neither shows nor teaches the step of uploading prescription data defining a prescription into a carrier through an interface. This step, as alluded to above, was missing from Gombrich and Leigh-Spencer. Further, this Article fails to teach or suggest the step of downloading prescription data from a carrier through an interface at a

pharmacy. Instead, the Article contains a detailed discussion of encryption technologies, but does not cure the deficiencies in Gombrich or Leigh-Spencer. As such, Claim 7 is allowable over the combination of Gombrich, Leigh-Spencer, and the article published by the Computer Science Telecommunications Board.

The Computer Science Telecommunications Board makes reference to the state of encryption technologies, but there is no teaching or suggestion whatsoever of using this encryption technology in combination with any of the elements set forth as claimed elements of the applicants' invention. Specifically, there is no suggestion that this technology could be used in combination with a digital prescription carrier that may receive uploaded wholly intangible prescription data for later access by a pharmacist. Indeed, this article contains no suggestion that this encryption technology could be used in combination with a carrier that can be transferred by a patient to a pharmacist. Without this suggestion, the cited art fails to establish prima facie obviousness with respect to claim 7. As such, claim 7 is allowable over the cited art.

Claims 8-13, which further limit allowable claim 7, should also be allowed for their separate, patentable limitations.

C.

THE FINAL REJECTION ERRONEOUSLY REJECTED CLAIMS 14- 18 AS OBVIOUS OVER THE COMBINED TEACHINGS OF GOMBRICH, LEIGH-SPENCER, AND AN ARTICLE PUBLISHED BY THE COMPUTER SCIENCE TELECOMMUNICATIONS BOARD BECAUSE THESE REFERENCES FAIL TO COMBINE TO ESTABLISH PRIMA FACIE OBVIOUSNESS OF THE CLAIMED COMBINATION

1.

THE APPLICANT RE-WROTE CLAIM 14 IN ACCORD WITH THE INSTRUCTIONS OF THE SUPERVISORY EXAMINER, WHO AGREED THAT THE CLAIM, AS SUBMITTED, WOULD DISTINGUISH OVER THE ART

Claim 14 has been re-written to incorporate the written instructions and recommendations given by Examiner Thomas at the interview of May 28, 2003. There can be little explanation as to why a supervisory examiner would recommend the amendment of a claim, then agree that the same distinguishes over the cited art, then sign a rejection of his own amendment based upon the same art that the supervisory examiner agreed was distinguished. A careful reading of authority finds no sources indorsing this questionable practice on behalf of any member of the examining corps.

2.

**GOMBRICH, LEIGH-SPENCER, AND THE ARTICLE
PUBLISHED BY THE COMPUTER SCIENCE
TELECOMMUNICATIONS BOARD FAIL TO SHOW, TEACH,
OR SUGGEST EACH AND EVERY CLAIMED LIMITATION**

Notwithstanding these curious tactics, a fresh look at claim 14 by the Board will establish allowability over the cited art. To wit, Claim 14 is drawn to a digital prescription carrier apparatus including, inter alia, input/output (I/O) interface circuitry positioned in the housing and interfaced to a CPU, the I/O circuitry being capable of interfacing the CPU to an external computer to exchange data therewith. Claim 14 further requires a CPU and the I/O circuitry cooperate to enable uploading, by a prescriber, of the prescription data into memory circuitry, and uploading, by a prescriber, of the prescription data into the memory circuitry, and downloading of the prescription data at a pharmacy .

Curiously, the Final Rejection asserts that Gombrich discloses this element. The passages cited have no mention whatsoever that the orifice wherein data is taken in by the bar code reader can be an input/output interface. The bar code reader of the Portable Handheld Patient Terminal (PHPT) contains *two separate interfaces*: one interface wherein data is gathered by the bar code reader (bar code wand 120), and second interface (RF Link 124) wherein the PHPT transmits data to the hospital's central computer system. Clearly, this teaches away from an input/output interface wherein data is uploaded and downloaded to and from the carrier.

The Final Rejection further asserts that the 'components of claim 14 have been fully addressed in the rejection of method claims 1 and 7 above, and therefore ... claim 14 is rejected for the same reasons...' As pointed out above, the rejection of claims 1 and 7 should be reversed. For the same reasons as pointed out with regard to the rejections of claims 1 and 7, Claim 14 is allowable over the cited art. This rejection of Claim 14 should be reversed.

Claims 15-18, which further limit claim 14, should likewise be allowed for their separate, patentable limitations.

III.

**THE EXAMINER ERRONEOUSLY REJECTED CLAIMS 1,7,
AND 14 AS UNPATENTABLE UNDER 35 U.S.C. §132,
BECAUSE THE MATERIAL ADDED BY AMENDMENT
WAS NOT NEW MATTER.**

The Final Rejection asserted that the following limitations, which were added by amendment on June 13, 2003, introduced new matter into the specification. Specifically, the rejection sets forth the following limitations, and alleges each to be improper new matter:

- i. encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software; and,
- ii. decrypting prescription data from indecipherable form into a form that would be decipherable; and,
- iii. wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact; and,

- iv. the data being in a wholly intangible form.

Each of the above-stated bases for the new-matter rejection should be reversed because each limitation added by amendment is **EXPRESSLY** set forth in the original specification; alternatively, each is **INHERENTLY DISCLOSED** in the original specification.

A.

THE AMENDMENTS SUBMITTED ON JUNE 13, 2003 SET FORTH MATTER THAT WAS EXPRESSLY SET FORTH IN THE INITIAL DISCLOSURE

1.

THE LIMITATION “ENCRYPTING PRESCRIPTION DATA DEFINING A PRESCRIPTION SO THAT THE DATA WOULD BE INDECIPHERABLE WITHOUT APPROPRIATE COMPUTER DECRYPTION SOFTWARE” WAS SET FORTH IN THE ORIGINAL SPECIFICATION

With regard to limitation (i) set forth above, attention is invited to the following portions of the original specification:

Access can be restricted by the use of simple passwords. However, the data within the prescription carrier of the present invention is preferably encrypted using one or more encryption keys or digital signatures which are available only to the physician and the pharmacist, but not the patient. See, p. 5, lines 10-15.

The external computer 44 executes special software (not detailed herein) to access the carrier 1. See, p. 12, line 19-20.

if communications have been established at 64, a security test 65 is entered, requiring the entry of a valid encryption key or password. If the entered encryption key or password is not correct, communication between the carrier 1 and the external computer 44 is disabled at 66 and control is passed... See, p. 14, lines 12-16.

... if the encryption key or password is valid, a communication mode test 67 is conducted to determine if a pharmacy mode 68 or a doctor mode 69 is to be entered. In the pharmacy mode 68, the pharmacist is allowed to access all the current prescriptions, to decrement refill counts of certain prescriptions, and to view patient information which is stored in the carrier. The doctor mode 69 includes all pharmacy mode privileges and additionally allows entry and deletion of prescriptions.. See, p. 14, line 18 – p 15, line 3.

Clearly, the original specification contains ample disclosure of the method step(s) of encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software. As such, the examiner should be reversed on this issue.

2.

**THE LIMITATION “DECRYPTING PRESCRIPTION
DATA FROM INDECIPHERABLE FORM INTO A
FORM THAT WOULD BE DECIPHERABLE” WAS
SET FORTH IN THE ORIGINAL SPECIFICATION**

With regard to element (ii) set forth above, attention is invited to the following passages of the original specification:

... to provide such a system including a portable prescription carrier apparatus in which data representing the prescription is uploaded by a physician and downloaded by a pharmacist to fill the prescription... See, p. 6, lines 5 –9.

... to provide such a carrier apparatus in which prescription data therein is encrypted and which cannot be decrypted by the patient to thereby prevent falsification or counterfeiting of the prescription data therein... See, p. 6, lines 19-22.

The above provisions of the original specification provide ample support for the amendment of a claim to include the method step(s) of decrypting prescription data from indecipherable form into a form that would be decipherable. As such, this rejection should be reversed.

3.

**THE LIMITATION “THE UPLOADING AND
DOWNLOADING STEPS ARE EACH
ACCOMPLISHED BY A DATA TRANSFER THAT
OCCURS WITHOUT PHYSICAL CONTACT” WAS
SET FORTH IN THE ORIGINAL SPECIFICATION**

With regard to element (iii) set forth above, attention is invited to the following passages of the original specification:

‘... IR links are provided on some laptop computers, as well as on some peripheral devices, such as printers, so that a document can be printed from the laptop computer by the printer without a conductive connection. In the carrier 1, the IR link port is used to upload prescription data into the carrier and to download such data from the carrier 1.

The specification expressly sets forth that data may be transferred using an IR link in order to facilitate a transfer without a conductive connection. One having skill in the pertinent art understands a conductive connection to occur when there is physical contact between charged elements. As such, the amendment of the claims to include the method step(s) of uploading and downloading steps by a data transfer that occurs without physical contact is explicitly set forth in the specification as filed. This rejection should be reversed.

4.

**THE LIMITATION “SAID DATA BEING IN A
WHOLLY INTANGIBLE FORM” WAS SET FORTH
IN THE ORIGINAL SPECIFICATION**

With regard to item (iv) set forth above, attention is invited to the following passage(s) of the specification, as initially filed:

The carrier 1 has utility as a sole prescription carrier or as a digital version of a conventional signed prescription form. (emphasis added) See, p. 15, lines 9-11.

The carrier of the present invention complements the functions of current paper-based method of filling prescriptions ... See, p. 15, lines 14-16.

The term, “intangible” means “*Incapable of being perceived by the senses.*” See, e.g., Webster’s Unabridged Dictionary, 8th Ed. The term “digital” means: “Expressed in numerical form, esp. in a form to be used by a computer.” Id.

It is submitted that the term “digital” as it is commonly used in the art, describes a data form that is electronically readable by a computer, but not perceivable by the human senses. As such, the limitation that the data be in a wholly intangible form finds support in the original specification. This rejection should be reversed.

B.

**THE AMENDMENTS SUBMITTED ON JUNE 13, 2003 SET
FORTH MATTER THAT WAS INHERENTLY DISCLOSED
IN THE INITIAL DISCLOSURE**

Even if the Board should find that the Applicant failed to expressly disclose sufficient information to provide support for the amendment(s) submitted on June 13, 2003, the rejection should be reversed for yet another, equally-valid reason.

It is well-settled law that an amendment submitted by an applicant that further describes a feature that is already present in the specification is NOT IMPROPER NEW MATTER, provided that the further description would be found, by one having skill in the art, to be an quality inherent in the initial disclosure. See, e.g. *Kennecott Corp v. Kyocera International*, 835 F2d 1419 (Fed Cir 1987). In the instant case, it is submitted that each of the features that are objected to as “new matter” were at least inherently disclosed in the initial specification.

1.

**THE LIMITATION “ENCRYPTING
PRESCRIPTION DATA DEFINING A
PRESCRIPTION SO THAT THE DATA WOULD
BE INDECIPHERABLE WITHOUT
APPROPRIATE COMPUTER DECRYPTION
SOFTWARE” WAS INHERENTLY
DISCLOSED BY THE ORIGINAL
SPECIFICATION**

With specific regard to limitation (i), the applicant submits that the matter inserted by amendment is merely the injection of the commonly-understood definition of the term “encrypt.” It is submitted that the terms “encrypt” and “decrypt” were freely used throughout the specification and claims of the originally filed application.

The term “encrypt” means *“to alter using a secret code so as to be unintelligible to unauthorized parties.”* See, Websters Unabridged Dictionary, 8th Ed. Addition of the phrase *“encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software”* clarifies the use of the term “encrypt” to denote a meaning that is well-known and commonly used by those having skill in the applicable art. Consequently, the added verbiage constitutes matter that was well-known to be an inherent aspect of the initially-filed disclosure. As such, this rejection should be reversed.

2.

**THE LIMITATION “DECRYPTING
PRESCRIPTION DATA FROM INDECIPHERABLE
FORM INTO A FORM THAT WOULD BE
DECIPHERABLE” WAS INHERENTLY
DISCLOSED BY THE ORIGINAL
SPECIFICATION**

With specific regard to limitation (ii) set forth above, the applicant submits that the term “decrypt” was used throughout the original specification (including the claims), as originally filed. The term “decrypt” means “*to decipher; to decode.*” Id. The addition of the limitation: “*decrypting prescription data from indecipherable form into a form that would be decipherable*” therefore further defines and explains a feature that was inherently set forth in the initially-filed specification. As such, the addition of this phrase does not introduce new matter. This rejection should be reversed.

3.

**THE LIMITATION “*THE UPLOADING AND
DOWNLOADING STEPS ARE EACH
ACCOMPLISHED BY A DATA TRANSFER THAT
OCCURS WITHOUT PHYSICAL CONTACT*” WAS
INHERENTLY DISCLOSED BY THE ORIGINAL
SPECIFICATION**

With specific regard to limitation (iii) set forth above, the applicant submits that the added limitation of “a data transfer that occurs without physical contact” was inherently set forth in the initial specification. To wit, the discussion of an “infrared data transfer” through an infrared data interface wherein data can be transferred from one component to another without a conductive connection clearly implies that a data may be transferred without physical contact between components. See, e.g. Specification, p. 11, line 14 – p. 12, line 6. Indeed, this method of “contactless” transfer wherein the uploading and downloading steps are each accomplished by a data transfer that occurs without a conductive connection is contrasted with the traditional methods of transferring data, such as by RS232 or USB ports. Clearly, the Specification inherently teaches contrasting methods of data transfer including conductive (i.e., contact) transfer methods and non-conductive (i.e., non-contact) transfer methods. Any claim that this element is neither taught nor suggested in the original specification is wrong. This rejection should be reversed.

4.

**THE LIMITATION “SAID DATA BEING IN A
WHOLLY INTANGIBLE FORM” WAS
INHERENTLY DISCLOSED BY THE
ORIGINAL SPECIFICATION**

With regard to limitation (iv) set forth above, the applicant submits that a well-known property of “digital data” or “computer data,” as understood by those having skill in the art, is that digital data is not humanly perceptible. Instead, this data is in a form that is not capable of being read or perceived by humans, but is wholly intangible. The addition of “*data being in a wholly intangible form*” therefore further defines and denotes features that were at least inherently present in the originally-filed specification. This rejection should be reversed.

C.

**THE AMENDMENTS SUBMITTED ON JUNE 13, 2003
SET FORTH MATTER THAT DISCLOSED IN
MATERIAL INCORPORATED BY REFERENCE INTO
THE INITIAL DISCLOSURE**

Attention is invited to the fact that the complete disclosures of United States Patents 4,200,770 to Hellman, et al, and 5,537,475 to Micali have been incorporated into the original specification by reference. See, Specification, p 5, lines 19-20. Each of these patents teaches and fully sets forth digital encryption and decryption technology in conjunction with the concept of electronic signatures.

Specifically, attention is invited to the following discourse contained within the Hellman '770 Patent:

The cryptographic device 15 enciphers the plaintext message P into an enciphered message or ciphertext C on line C that is transmitted by converser 11 through the insecure channel 19; the ciphertext C is received by converser 12 and deciphered by cryptographic device 16 to obtain the plaintext message P. An unauthorized party or eavesdropper 13 is assumed to have a cryptographic device 17 and to have access to the insecure channel 19, so if he knew the key K he could decipher the ciphertext C to obtain the plaintext message.

See, Column 3, lines 57-67

Further attention is invited to the following disclosure set forth in the Hellman '770 patent:

...enciphering the message with said secure cipher key at the transmitter;
transmitting the enciphered message from the transmitter to the receiver; and
deciphering the enciphered message with said secure cipher key at the receiver

See, e.g., Claim 2.

In addition to the above-referenced passages from the Hellman '770 patent, the entire Micali '475 patent discusses an encryption and decryption technology that can be used to encipher and decipher electronic (i.e., intangible) data so that it would be unintelligible without a specific signature key.

These patents (Micali '475 and Hellman '770) provide ample support for the features introduced by amendment. Therefore, the rejection should be reversed.


IV.

CONCLUSION

For the foregoing reasons, the Applicant respectfully requests that the Board reverse the Final Rejection, and remand this matter back to the Supervisory Examiner with instructions to issue a Notice of Allowance of all pending claims.

The Commissioner is hereby authorized to charge any fee due for the full consideration or examination of this paper to Deposit Account Number 502643.


Respectfully Submitted,



David E. Herron II
USPTO Reg. No. 46,467
PO Box 2778
Kansas City, KS 66110
(913) 371-7011
FAX (913) 233-1600
ATTORNEY FOR APPLICANT

CERTIFICATE OF MAILING
37 CFR §1.10

IT IS HEREBY CERTIFIED THAT the above and foregoing document was deposited in the United States Express Mail bearing label number EU253214895US, postpaid and properly addressed to Mail Stop Appeal, Commissioner of Patents, PO Box 1450 Alexandria VA 22313-1450 on January 26, 2004.



David E. Herron II #46,467

APPENDIX

1. A method for conveying a prescribed medication to a patient, the method comprising the steps of:

providing a digital prescription carrier including a read/write memory and an infrared communication interface;

encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software;

uploading, by a prescriber, the prescription data into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;

transferring said carrier by a patient to a pharmacy;

downloading said prescription data from said carrier through said interface at said pharmacy;

decrypting said prescription data from indecipherable form into a form that would be decipherable; and

filling said prescription at said pharmacy; wherein,

the uploading and downloading steps are each accomplished by a data transfer that occurs without physical contact.

2. A method as set forth in Claim 1, further including the step of entering a first access code into said carrier to enable access to said prescription data prior to said uploading step.

3. A method as set forth in Claim 1, further including the steps of:
 - (a) operating a digital clock/calendar within said carrier to generate internal values of time and date;
 - (b) providing said carrier with a prescription compliance switch interfaced to said clock/calendar;
 - (c) operating said compliance switch by a patient upon taking a medication specified by said prescription; and
 - (d) storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.
4. A method as set forth in Claim 3, further including the steps of:
 - (a) providing said carrier with an annunciator element;
 - (b) entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by prescription;
 - (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
 - (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.

5. A method as set forth in Claim 2, further including the step of entering a second access code into said carrier to enable access to said prescription data prior to said downloading step.

6. A method as set forth in Claim 1, further including the steps of:

- (a) uploading prescription data defining a plurality of prescriptions for a plurality of medications into said carrier through said interface;
- (b) downloading said prescription data through said interface; and
- (c) filling each of said prescriptions defined by said prescription data.

7. A method for conveying a prescribed medication to a patient, the method comprising the steps of:

providing a digital prescription carrier including a read/write memory and a communication interface;

entering a first access code into said carrier to enable software access thereto;

uploading prescription data defining a prescription, said data being in a wholly intangible digital form, into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;

encrypting said prescription data so that said data would be indecipherable without appropriate computer decryption software;

transferring said carrier by a patient to a pharmacy;

entering a second access code into said carrier to enable software access thereto;

downloading said prescription data, said data being in a wholly intangible digital form, from said carrier through said interface at said pharmacy;

decrypting the prescription data to convert the data into an intelligible form;

and filling said prescription by said pharmacist.

8. A method as set forth in Claim 7, further including the steps of:
 - (a) operating a digital clock/calendar within said carrier to generate internal values of time and date;
 - (b) providing said carrier with a prescription compliance switch interfaced to said clock/calendar;
 - (c) operating said compliance switch by a patient upon taking a medication specified by said prescription; and
 - (d) storing in a compliance memory within said carrier respective values of time and date occurring upon operation of said compliance switch.
9. A method as set forth in Claim 8, further including the steps of:
 - (a) providing said carrier with an annunciator element;
 - (b) entering into said carrier by said pharmacist schedule data defining a prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by said prescription;

- (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
- (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and schedule date.

10. A method as set forth in Claim 9 wherein said annunciator element includes a vibrating element.

11. A method as set forth in Claim 7, wherein said communication interface includes an infrared data communication interface.

12. A method as set forth in Claim 7, further including the steps of:

- (a) uploading, by a physician, prescription data defining a plurality of prescriptions for a plurality of medications to be taken on a plurality of schedules into said carrier through said interface;
- (b) downloading, by a pharmacist, said prescription data through said interface; and
- (c) filling each of said prescriptions defined by said prescription data.

13. A method as set forth in Claim 7, further including the steps of:

- (a) providing said carrier with an annunciator element;
- (b) entering into said carrier, by said pharmacist for each of said prescriptions, schedule data defining a respective prescription schedule comprising a plurality of sets of schedule times and dates at which a patient is to take a medication specified by the respective prescription;

- (c) periodically comparing within said carrier said internal values of time and date with said schedule times and dates; and
 - (d) activating said annunciator element upon said internal values of time and date matching a set of said schedule time and date.
14. A digital prescription carrier apparatus comprising:
- a carrier housing;
 - a central processing unit (CPU) positioned within said housing;
 - a display device positioned on said housing, interfaced to said CPU, and capable of displaying alphanumeric characters;
 - input/output (I/O) interface circuitry positioned in said housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith;
 - data memory circuitry positioned within said housing;
 - encrypting software for scrambling prescription data that represents a prescription into a form that is unintelligible and unreadable, said encrypting software further capable of converting encrypted prescription data to a readable form; and,
 - prescription software stored in said memory to be processed by said CPU,
- wherein,
- the CPU and the I/O circuitry cooperate to enable uploading, by a prescriber, of the prescription data into said memory circuitry, and downloading of said prescription data at a pharmacy.

15. A digital prescription carrier apparatus as set forth in Claim 14, further including:

- (a) a real-time clock/calendar positioned within said housing and interfaced to said CPU;
- (b) an alert device positioned within said housing and interfaced to said CPU; and
- (c) said prescription software cooperating with said prescription data, said clock/calendar, and said alert device to cause activation of said alert device when a dose of medication prescribed by said prescription data is to be taken.

16. A digital prescription carrier apparatus as set forth in Claim 15, further including:

- (a) a compliance switch positioned on said housing and interfaced to said CPU; and
- (b) said prescription software cooperating with said compliance switch to record in said data memory circuitry an occurrence of the operation of said compliance switch subsequent to activation of said alert device.

17. A digital prescription carrier apparatus as set forth in claim 15 wherein said alert device includes at least one of:

- (a) a sonic alert device interfaced to said CPU; or
- (b) a vibrating alert device interfaced to said CPU.

18. A digital prescription carrier apparatus as set forth in Claim 14, further including:

- (a) a plurality of key switches positioned on said housing and interfaced to said CPU;
- (b) said prescription software causing uploaded prescription data to generate a schedule of dose times for a medication represented by said prescription data; and
- (c) operation of said key switches enabling review of said schedule of dose times for said medication in cooperation with said display device.

19. A digital prescription carrier apparatus as set forth in Claim 14 wherein said I/O interface circuitry includes an infrared data link.

20. A method as set forth in Claim 1, further including the step of entering a second access code into said carrier to enable access to said prescription data prior to said downloading step.

- 21 A method as set forth in Claim 2, further including the steps of:
- endowing a prescriber with the first access code;
 - updating, by a prescriber, of prescription information including at least one of
 - deleting a piece of stored prescription data;
 - adding a new piece of stored prescription data;
 - changing a piece of stored prescription data;
 - endowing the pharmacist with the second access code; and,
 - updating, by the pharmacist, of prescription information including at least one of
 - noting the filling of a prescription;
 - reducing the number of refills remaining for a piece of stored prescription data; or,
 - updating patient information.